PATENT
13024/35946

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on this date:
McMICHAEL et al.	
Serial No.: 09/495,186	
Filed: February 1, 2000	
For: TREATMENT OF SYMPTOMS OF ASTHMA, ALLERGIES AND OTITIS MEDIA	**March 8, 2004**
Group Art Unit: 1633	Jeffrey S. Sharp Registration No. 31,879
Examiner: Michael C. Wilson	Attorney for Applicants

APPLICANTS' RESPONSE AFTER FINAL REJECTION UNDER 37 C.F.R. §1.116

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is in response to the Office Action dated September 11, 2003 in the above-identified application in which all pending claims (15-19) stand rejected under 35 U.S.C. §112 (first and second paragraphs). Reconsideration and allowance of those claims is solicited in light of the following remarks. This response is timely filed as a petition for three months extension of time until March 11, 2004 is submitted herewith.

I. The Outstanding Rejections

Claims 15-19 stand rejected under 35 U.S.C. §112 (first paragraph) for lack of enablement.

Claims 15-19 stand rejected under 35 U.S.C. §112 (second paragraph) as being indefinite.

II. Patentability Arguments

A. The Lack of Enablement Rejections of Claims 15-19 Under 35 U.S.C. §112 (First Paragraph) Should Be Withdrawn.

The rejections of claims 15-19 under 35 U.S.C. §112 (first paragraph) for lack of enablement should be withdrawn because Applicant's invention is not an antibacterial method but is instead directed to treatment of the symptoms of otitis media which may or may not occur in the presence of infection. For this reason, the statement in the Office Action that: "the person of skill in the art would conclude that the only management methods for treating otitis media itself, ... are those that result in the reduction of bacteria or virus numbers" (emphasis added) is not correct. In fact, recent news reports suggest that the American Academy of Pediatrics and the American Academy of Family Physicians will presently recommend against administration of antibiotics as a treatment for most otitis media in children. (http://health.yahoo.com/search/healthnews?lb=s&p=id%3A54762, See Appendix A attached hereto)

Otitis media can be classified as acute otitis media which is otitis media in the presence of infection and serous otitis media (also known as "otitis media with effusion," OME) which is without signs of infection. (See Managing Otitis Media With Effusion in Young Children, Pediatrics, Vol. 94, No. 5 November 1995 attached hereto as Appendix B) Moreover, the art acknowledges that Otitis Media with Effusion (serous otitis media) can be in the absence of concurrent infection when it instructs against antibiotic treatment. (See Ipp, Treatment of Otitis media: An Update, Revisions and Reconsideration of Established Guidelines, http://www.toronto.ca/kids/otitmedi.htm 11/24/2003 attached hereto as Appendix C which teaches that "[a]ntibiotic treatment for serous otitis media (otitis media with effusion, OME) is not necessary and should be eliminated except for specific indications ...".)

Thus, the assumption regarding the need to reduce numbers of bacteria underlying the rejection is misplaced because the presence of bacteria does not necessarily correlate with otitis media symptoms. As discussed in the preceding Response, the symptoms of otitis media are thought to be the consequence of an inflammatory response to infection which inflammatory response is not immediately relieved when the infection is eliminated. While otitis media is frequently secondary to infection, the elimination or treatment of infection is neither necessary nor sufficient to treat the symptoms of otitis media. Accordingly, whether

the administration of DNA to a subject reduces bacteria count is irrelevant to the issue of whether the therapy effectively treats pain or other symptoms of otitis media.

Applicants have demonstrated the utility of their invention for treatment of the symptoms of both acute otitis media (with infection) (see Examples XX, XXI, XXII, XXVIII and XXIX), and serous otitis media (see Examples XXIII, XXIV, XXVI, and XXVII) without apparent infection. The success of Applicants' method in treating symptoms both with and without infection demonstrates that the mode of action is not an antibacterial mode but suggests that the mode might be an anti-inflammatory one or relate to clearance of fluid (See related U.S. Patents Nos. 6,096,721, 5,955,442, 5,726,160, and parent patent 6,100,244 relating in one manner or another to treatment of congestion or other respiratory conditions.)

Applicants therefore traverse the proposition that the administration of DNA topically into the ear does not effect "a change in symptoms" and dismiss the relevance of whether such administration should affect the amount of pathogen in the ear.

Accordingly, no evidence or logic has been presented that casts doubt on the efficacy of the treatment claimed by Applicant and described in Examples XX through XXIX of the specification. Accordingly, the rejections of claims 1-7 under 35 U.S.C. §112 (first paragraph) should be withdrawn.

B. The Rejections of Claims 15-19 Under 35 U.S.C. §112 (Second Paragraph) Should Be Withdrawn.

The rejection of claims 15-19 under 35 U.S.C. §112 (second paragraph) as being indefinite should be withdrawn as the language "so as to not effect gene transfer" is clear and understandable to those of skill in the art in light of the teachings of the specification. The invention relates to the administration of DNA for the treatment of symptoms of otitis media but does not perform this method by transfection or otherwise by the practice of gene expression or gene therapy. In this context it is clear that "so as not to effect gene transfer" excludes transfection and gene therapy but encompasses the topical administration of DNA by transfer of DNA from a bottle to a subject.

It was in the course of prosecution of a related case in which clarification was sought by the Patent Office Examiner of whether the mechanism of action through which DNA administration performed its function was by gene therapy effected by gene transfer. In response to that inquiry the claim language in that application was amended to recite that the DNA was administered in a manner "so as to not effect gene transfer" in great-grandparent application U.S. Serial No. 08/755,092 which issued as U.S. Patent No. 5,726,160.

Moreover, each of, 6,096,721, 5,955,442, 5,726,160, and parent patent 6,100,244 comprise this identical language in their claims. For the foregoing reasons, one of skill would understand what is encompassed by the claims of the invention and what is not and the rejection under 35 U.S.C. §112 (second paragraph) should be withdrawn.

CONCLUSION

For all of the foregoing reasons, the rejections should now be withdrawn and allowance of all pending claims 15-19 is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, he is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

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